K101886

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Miami Beach, FL 33139
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JUL 2 1 2011

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DSC/ALF Spinal System
510(k) Summary
June 2010

I. **Company:** **Sintea Plustek, LLC.**
407 Lincoln Rd. Suite 10L
Miami Beach, FL 33139
(305) 673-6226

II. **Proprietary Trade Name:** **DSC/ALF System**

Regulation Number: **888.3060**

Regulation Name: **Spinal Intervertebral Body Fixation Orthosis**

Product Code: **MQP, KWQ**

III. Product Description

This 510(k) consists on the submission to add additional lengths and cross-sections, an improved locking mechanism, cage body redesign, and end-plate characteristics changes to a previously cleared system. The DSC/ALF Spinal System provides two basic components: A VBR (DSC) and an anterior lateral fixation plate (ALF). The DSC has a hollow internal module that can slide in relation to an external module, which enables the former to be locked in the most suitable position by means of two screws. These screws are inserted into two tooth rails on the internal cage, on both the anterior and posterior part, and mechanically lock the two modules. Both modules have endplates that optimize the contact with the vertebral bodies between which the device is inserted, thus ensuring better primary stability. The cages present a symmetrical geometry in order to make device placement simpler for the surgeon. The ALF is composed of two plates that connect to the anterior side of a vertebra by two screws. The two plates are connected by a rod. All components of the DSC/ALF Spinal System are made of medical grade titanium alloy (Ti-6Al-4V) as described by ASTM Standard F136.

IV. Indications

The DSC/ALF Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The DSC/ALF Spinal System is to be used with supplemental fixation. Specifically, the DSC/ALF spinal system is to be used with the anterior lateral plate that is included in the system, and may also be used with the Sintea Biotech PLS Spinal System. Additionally, the DSC/ALF spinal system is intended to be used with autograft.

V. Performance Data – Overview

1. Static compression – This test on the new device achieved better results than those of the predicate device.
2. Static torsion – This test on the new device achieved better results than those of the predicate device.

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3. Subsidence – This test on the new device achieved better results than those of the predicate device.
4. Expulsion – This test on the new device achieved comparable results to those of the predicate device.
5. Fatigue compression – This test on the new device achieved better results than those of the predicate device.
6. Fatigue torsion - This test on the new device achieved comparable results to those of the predicate device.

Testing standards followed:
ASTM F2077
ASTM F2267

VI. Substantial Equivalence
Sintea Plustek, LLC. believes that the additions to the DSC/ALF Spinal System are substantially equivalent to the Sintea Biotech's DSC/ALF Spinal System (K070181) with respect to functional design, indications for use, principles of operation, performance, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sintea Plustek, LLC
% Ms. Danielle Wernikowski
407 Lincoln Road, Suite 10L
Miami Beach, FL 33139

JUL 21 2011

Re: K101886
Trade/Device Name: DSC/ALF Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP, KWQ
Dated: July 06, 2011
Received: July 11, 2011

Dear Ms. Wernikowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

E. N. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sintea Plustek, LLC.
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Indications for Use

510(k) Number (if known): K101886

Device Name: DSC/ALF Spinal System

Indications for Use:

The DSC/ALF Spinal System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The DSC/ALF Spinal System is to be used with supplemental fixation. Specifically, the DSC/ALF spinal system is to be used with the anterior lateral plate that is included in the system, and may also be used with Sintea Biotech's PLS Spinal System. Additionally, the DSC/ALF spinal system is intended to be used with autograft.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101886

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